

## Food and Drug Administration, HHS

## § 610.62

(e) *Visual inspection.* When the label has been affixed to the container a sufficient area of the container shall remain uncovered for its full length or circumference to permit inspection of the contents.

[38 FR 32056, Nov. 20, 1973, as amended at 47 FR 22518, May 25, 1982; 63 FR 66400, Dec. 1, 1998]

EFFECTIVE DATE NOTE: At 67 FR 4907, Feb. 1, 2002, § 610.60 was amended in paragraph (a)(6) by removing the phrase “Caution: Federal law prohibits dispensing without prescription,” and by adding in its place the phrase “Rx only”, effective April 2, 2002.

### § 610.61 Package label.

The following items shall appear on the label affixed to each package containing a product:

- (a) The proper name of the product;
- (b) The name, address, and license number of manufacturer;
- (c) The lot number or other lot identification;
- (d) The expiration date;
- (e) The preservative used and its concentration, or if no preservative is used and the absence of a preservative is a safety factor, the words “no preservative”;
- (f) The number of containers, if more than one;
- (g) The amount of product in the container expressed as (1) the number of doses, (2) volume, (3) units of potency, (4) weight, (5) equivalent volume (for dried product to be reconstituted), or (6) such combination of the foregoing as needed for an accurate description of the contents, whichever is applicable;
- (h) The recommended storage temperature;
- (i) The words “Shake Well”, “Do not Freeze” or the equivalent, as well as other instructions, when indicated by the character of the product;
- (j) The recommended individual dose if the enclosed container(s) is a multiple-dose container;
- (k) The route of administration recommended, or reference to such directions in an enclosed circular;
- (l) Known sensitizing substances, or reference to an enclosed circular containing appropriate information;
- (m) The type and calculated amount of antibiotics added during manufacture;

(n) The inactive ingredients when a safety factor, or reference to an enclosed circular containing appropriate information;

- (o) The adjuvant, if present;
- (p) The source of the product when a factor in safe administration;
- (q) The identity of each microorganism used in manufacture, and, where applicable, the production medium and the method of inactivation, or reference to an enclosed circular containing appropriate information;
- (r) Minimum potency of product expressed in terms of official standard of potency or, if potency is a factor and no U.S. standard of potency has been prescribed, the words “No U.S. standard of potency.”

(s) The statement: “Caution: Federal law prohibits dispensing without prescription,” for prescription biologicals.

[38 FR 32056, Nov. 20, 1973, as amended at 47 FR 22518, May 25, 1982; 55 FR 10423, Mar. 21, 1990]

EFFECTIVE DATE NOTE: At 67 FR 4907, Feb. 1, 2002, § 610.61 was amended in paragraph (s) by removing the phrase “Caution: Federal law prohibits dispensing without prescription,” and by adding in its place the phrase “Rx only”, effective April 2, 2002.

### § 610.62 Proper name; package label; legible type.

(a) *Position.* The proper name of the product on the package label shall be placed above any trademark or trade name identifying the product and symmetrically arranged with respect to other printing on the label.

(b) *Prominence.* The point size and typeface of the proper name shall be at least as prominent as the point size and typeface used in designating the trademark and trade name. The contrast in color value between the proper name and the background shall be at least as great as the color value between the trademark and trade name and the background. Typography, layout, contrast, and other printing features shall not be used in a manner that will affect adversely the prominence of the proper name.

(c) *Legible type.* All items required to be on the container label and package label shall be in legible type. “Legible type” is type of a size and character

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which can be read with ease when held in a good light and with normal vision.

### § 610.63 Divided manufacturing responsibility to be shown.

If two or more licensed manufacturers participate in the manufacture of a biological product, the name, address, and license number of each must appear on the package label, and on the label of the container if capable of bearing a full label.

[64 FR 56453, Oct. 20, 1999]

### § 610.64 Name and address of distributor.

The name and address of the distributor of a product may appear on the label provided that the name, address, and license number of the manufacturer also appears on the label and the name of the distributor is qualified by one of the following phrases: "Manufactured for \_\_\_\_\_", "Distributed by \_\_\_\_\_", "Manufactured by \_\_\_\_\_ for \_\_\_\_\_", "Manufactured for \_\_\_\_\_ by \_\_\_\_\_", "Distributor: \_\_\_\_\_", or "Marketed by \_\_\_\_\_". The qualifying phrases may be abbreviated.

[61 FR 57330, Nov. 6, 1996]

### § 610.65 Products for export.

Labels on packages or containers of products for export may be adapted to meet specific requirements of the regulations of the country to which the product is to be exported provided that in all such cases the minimum label requirements prescribed in § 610.60 are observed.

## PART 630—GENERAL REQUIREMENTS FOR BLOOD, BLOOD COMPONENTS, AND BLOOD DERIVATIVES

AUTHORITY: 21 U.S.C. 321, 331, 351, 352, 355, 360, 371; 42 U.S.C. 216, 262, 264.

SOURCE: 66 FR 31176, June 11, 2001, unless otherwise noted.

### § 630.6 Donor notification.

(a) *Notification of donors.* You, an establishment that collects blood or blood components, must make reasonable attempts to notify any donor, in-

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cluding an autologous donor, who has been deferred based on the results of tests for evidence of infection with a communicable disease agent(s) as required by § 610.41 of this chapter; or who has been determined not to be suitable as a donor based on suitability criteria under § 640.3 or § 640.63 of this chapter. You must attempt to obtain the results of supplemental testing required under § 610.40(e) of this chapter prior to notifying a donor of the deferral. If notification occurs prior to receipt of such results, you must also notify a deferred donor of the results of the supplemental testing. You must notify a donor as described in paragraph (b) of this section.

(b) *Content of notification.* You must provide the following information to a donor deferred or determined not to be suitable as a donor as described in paragraph (a) of this section:

(1) That the donor is deferred or determined not to be suitable for donation and the reason for that decision;

(2) Where appropriate, the types of donation of blood or blood components that the donor should not donate in the future;

(3) Where applicable, the results of tests for evidence of infection due to communicable disease agent(s) that were a basis for deferral under § 610.41 of this chapter, including results of supplemental (i.e., additional, more specific) tests as required in § 610.40(e) of this chapter; and,

(4) Where appropriate, information concerning medical followup and counseling.

(c) *Time period for notification.* You must make reasonable attempts to notify the donor within 8 weeks after determining that the donor is deferred or determined not to be suitable for donation as described in paragraph (a) of this section. You must document that you have successfully notified the donor or when you are unsuccessful that you have made reasonable attempts to notify the donor.

(d) *Autologous donors.* (1) You also must provide the following information to the referring physician of an autologous donor who is deferred based on the results of tests for evidence of infection with a communicable disease